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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,222	03/23/2006	Daniel Raederstorff	22212USWO C038435/0196793	4962

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,222	RAEDERSTORFF ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-23* is/are pending in the application.

4a) Of the above claim(s) *1-13,16,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 15, 17, and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 28 January 2008 is acknowledged and has been entered. Claims 14, 15, 17 and 21-23 have been examined on the merits (claims 1-13, 16, 19, and 20 remain withdrawn from consideration).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 14, 15, 17, 21, and 22 are/stand rejected under 35 U.S.C. 102(b) as being anticipated by Cui (CN 1120953, Derwent Abstract provided), with evidence provided by Ahmad et al. (Nutrition Reviews, March 1999) and Ko (Jap. J. Pharmacol., 1980)* for the reasons set forth in the previous Office action.

Claim Rejections - 35 USC § 103

Claims 14, 15, 17, 21, and 22 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cui (CN 1120953, Derwent Abstract provided), with evidence provided by Ahmad et al. (Nutrition Reviews, March 1999) and Ko (Jap. J. Pharmacol., 1980)* for the reasons set forth in the previous Office action.

Applicants' arguments concerning the USC 102(b) and USC 103 rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections. Applicants argue that the Cui reference comprises other additional ingredients. However, the instantly claimed composition is one which comprises the instantly claimed ingredients. Accordingly, this open language (i.e., "comprising") permits the inclusion other ingredients therein. Applicants also argue that the Cui reference lacks an "identity of invention" with the claimed composition which comprises a catechin found in green tea and a PPARγ ligand - such as the elected species: ligustilide. However, for the reasons fully set forth in the previous Office action, the health-benefiting drink composition taught by Cui inherently comprises a catechin such as epigallocatechin gallate (inherently contained within green tea) and ligustilide (inherently contained within *Ligusticum wallichii*) - including being present within such a composition so as to provide the broad dosage ranges of each therein - as best understood by the claim language, as drafted (e.g.,, the instant claim language does not define in a positive manner as to what such a dosage of EGCG and/or ligustilide is in relation to). Applicants further argue the claim composition, as instantly amended, is now defined as being a pharmaceutical composition and that the Cui reference fails to disclose a pharmaceutical composition. However, the health-benefiting drink (having the various therapeutic functional effects disclosed therein) taught by Cui clearly reads upon a pharmaceutical composition. Applicants additionally argue that the claimed combination provides unexpectedly improved and superior results (e.g., as shown in Example 1 of the instant specification with respect to a therapeutic pharmaceutical composition comprising ligustilide and EGCG). Based on this argument, it would appear that Applicants' invention is predicated on an unexpected result, which typically involves synergism,

an unpredictable phenomenon highly dependent upon specific proportions and/or amounts of each particular ingredient (e.g., claimed in a positive manner so that the dosages of each ingredient which actually provide such unexpected results are clearly and adequately defined within the independent claim). However, please note that any mixture of ingredients embraced by the claims which does not exhibit an unexpected result (including the composition defined by the instant claim language, as drafted) is deemed obvious and, thus, unpatentable for the reasons set forth above.

* Again please note that the Ahmad et al. and Ko references are not being cited as prior art within the USC 102(b) and 103 rejection above but instead are being cited as evidence to show inherent properties of green tea and *Ligusticum wallichii* within the Cui composition.

Claims 14, 15, 17 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morre et al. (US 6,410,061) and Zhao (US 2003/0165580).

A pharmaceutical composition, including in the form of a solid unit dosage, comprising a green tea catechin such as epigallocatechin gallate and ligustilide is claimed.

Morre et al. beneficially teach a pharmaceutical composition (including, e.g., in a solid unit dosage form such as a tablet or capsule) useful for treating various cancers including ovarian cancer, which comprises one or more green tea catechins such as epigallocatechin gallate as the active ingredient(s) therein. Morre et al. also teach that an effective daily dosage of epigallocatechin gallate is about 0.15 mg to about 1500 mg per kg body weight (within the instantly claimed dosage amount - as best understood). See entire document including Abstract; col 6, line 29 - col 17, line 35; and claims. Morre et al. do not teach the inclusion of ligustilide therein.

Zhao beneficially teaches a pharmaceutical composition (including, e.g., in a solid unit dosage form such as a tablet or capsule) useful for treating/controlling gynecological diseases including cancers such as ovarian cancer, which comprises ligustilide as the active ingredient therein. Zhao also teaches that an effective daily dosage of ligustilide is 1-10 mg per kg body weight which - as disclosed by Zhao, corresponds to 50-500 mg/adult/dose for a 50 kg adult (within the instantly claimed dosage amount - as best understood). See entire document including Abstract, paragraphs [0017]-[0019], [0036]-[0037], [0090]-[0093], Examples, and claims.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose (i.e., for treating cancer including ovarian cancer) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518.; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular (e.g., active) ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him/her as a guide

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

Claims 14, 15, 17 and 21-23 are/stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-45 of copending Application No. 10/533,858.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending Application are drawn to compositions comprising epigallocatechin gallate and the non-elected species phytanic acid therein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 14, 15, 17 and 21-23 are/stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-24 of copending Application No. 10/556,199, in view of Hara et al. (US 5,318,986).

The instantly claimed invention is drawn to a pharmaceutical composition comprising a green tea catechin (such as epigallocatechin) and ligustilide therein, whereas the invention defined by the cited claims of Appl. No. '199 is drawn to a pharmaceutical composition (for the intended purpose of treating/preventing diabetes) comprising ligustilide. therein. Hara et al. teaches the use of a composition comprising epigallocatechin gallate (from green tea) for effectively treating diabetes (see entire document). Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the claimed anti-diabetic ligustilide pharmaceutical composition set forth in Appl. No. '199 with epigallocatechin gallate based upon the beneficial teachings provided by Hara et al. with respect to epigallocatechin gallate also being an effective anti-diabetic agent.

This is a provisional obviousness-type double patenting rejection.

Applicants' arguments concerning the provisional obviousness-type double patenting rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections. Applicants argue that while the Examiner acknowledges that the claims of the '858 application differ, the previous Office action failed to make clear why one of ordinary skill in the art would conclude the instantly claimed invention would have been obvious to those of the cited claims within copending Appl. '858. However, the provisional obviousness-type double patenting rejection above is deemed proper because the instantly recited claim language (including the recitation of non-elected species such as phytanic acid), is considered obvious over the cited claims of US Appl. '858.

With respect to the latter obviousness-type double patenting rejection above, Applicants argue that the Examiner only asserted in the previous Office action that making the combination of ligustilide with EGCG would have been obvious over the '199 application in view of Hara et al., and that the instantly claimed composition has been amended so as to now recite "wherein the composition is a pharmaceutical composition". However, the latter provisional obviousness-type double patenting rejection above is deemed proper for the reasons set forth therein - i.e., the instantly claimed invention is drawn to a pharmaceutical composition comprising a green tea catechin (such as epigallocatechin) and ligustilide therein, whereas the invention defined by the cited claims of Appl. No. '199 is drawn to a pharmaceutical composition (for the intended purpose of treating/preventing diabetes) comprising ligustilide therein. Hara et al. teaches the use of a composition comprising epigallocatechin gallate (from green tea) for effectively treating diabetes (see entire document). Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the claimed anti-diabetic ligustilide pharmaceutical composition set forth in Appl. No. '199 with epigallocatechin gallate based upon the beneficial teachings provided by Hara et al. with respect to epigallocatechin gallate also being an effective anti-diabetic agent.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The examiner assigned to this Application has changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655